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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,978	09/12/2000	Roger Hull	620-106	6992

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Nixon & Vanderhye
8th Floor
1100 North Glebe Road
Arlington, VA 22201-4714

EXAMINER	
MOONAN, FRANCIS P	
ART UNIT	PAPER NUMBER
1638	17

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/622,978	HULL ET AL.	
	Examiner	Art Unit	
	Francis P Moonan	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-20* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of a photocopy of Priority Document of United Kingdom Application No. 9804293.0 filed on 27 February 1998 is acknowledged. However, applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The first page of the specification should contain a paragraph under the title, indicating that the application is a 371 of PCT/GB99/00599 filed 26 February 1999, and claims priority to United Kingdom Application No. 9804293.0 filed on 27 February 1998 .

Claims 1-20 are examined in the Office Action that follows.

Specification

A substitute specification including the claims is required pursuant to 37 CFR 1.125(a) because line 3 of each page is too faint to be reproduced..

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-12, 16-17, and 20, are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed plant cell invention is a naturally occurring phenomena .

Claims 10-12 and 16-17 are broadly drawn to any cell or plant propagule of any species, comprising a genomic insertion of nucleic acids comprising a polynucleotide whose sequence varies in length and composition from SEQ ID NO:2. The broadly claimed plant cells comprising *Banana streak virus* (BSV) viral genomic sequence further comprising insertions in plant cells are naturally occurring phenomena, and comprise natural phenomena occurring as a result of a pararetroviral "life cycle" for Badnaviruses such as those designated as BSV. Jaskowitsch et al (1999. Proc. National Acad. Sci. (USA) 96(23:13241-13241-13246) teach for example in the abstract on page 13241 and page 13241, column 1, lines 1 to column 2, line 19 that pararetroviral sequences naturally occur in plants as dispersed repetitive sequences inserted in the genome, as part of the pararetroviral replication cycle involves insertion into plant genomes. Applicants acknowledge on page 55, lines 9-22 of the instant specification evidence that the BSV genomes are integrated into the banana genome, consistent with their designation as pararetroviral viruses, as disclosed for example on page 2, lines 8-16.

The plant and parts thereof, as claimed, have the same characteristics and utility as those found naturally and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim 20 is rejected under 35 U.S.C. 101 because the claimed recitation of a "[u]se of a nucleic acid vector", without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6, dependent on any one of Claims 1, 3, and 5, is confusing in the recitation of "and a non-Banana Streak Virus sequence". The claim is interpreted to recite that the promoter is "non-Banana Streak Virus" in origin, which while plausible, would appear to be contrary to the intent of the claims from which Claim 6 depends. Applicant is advised, that if intended, insertion of a comma after the "5" on line 3, and insertion of the term --transcribable--before "sequence" and after "Virus" on line 3 of the claim would direct the non-BSV sequence limitation to a sequence ligated to the promoter.

Claim 20 is vague and confusing in the recitation of ""[u]se of a nucleic acid vector ". Claim 20 provides for the use of"[u]se of a nucleic acid vector", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the 5' region of an isolated polynucleotide consisting of the sequence of SEQ ID:NO:2 as an operably linked promoter for transcription of heterologous genes in *Musa* species with said promoter, does not reasonably provide enablement for claims broadly drawn to the SEQ ID NO:2 promoter for expression of a transcribable sequence in all plant genotypes of all *Musaceae* or all plants and all plant cells or tissue types; or for any polynucleotide with the characteristic that it has a multitude of unspecified sequence

changes in said promoter as broadly claimed for all plant genotypes or tissue types of all *Musaceae* or all plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1-20 and 3- are broadly drawn to an isolated *Banana streak virus* (BSV) promoter sequence comprising SEQ ID NO:2 or any sequence variant or fragment thereof from any BSV strain of optionally at least 7.5% identical to SEQ ID NO:2 or hybridizable thereof under conditions at unspecified stringency, optionally ligated to a transcribable sequence; vectors; plants of any *Musaceae* or non-*Musaceae* species, and any plant part containing it; and methods of use to produce transformed plants.

The determination of promoter function of a variety of sequences or sequence fragments from a variety of *Badnavirus* strains is unpredictable, since strain differentiation of *Badnavirus* spp. (the genus to which BSV belongs) is unpredictable. Cabauatan et al (1999. J. Gen. Virology 80 :2229-2237 teach for example in the Abstract on page 2229 and Figures 2-3 on page 2234, the spontaneous generation of three variants of the *Rice tungro bacilliform virus* (RTBV), from passage virus to different rice plants in the same greenhouse. Cabauatan teach for example on page 2229, line 1 to page 2237, line 44; and page 2236, lines 11 to page 2237, line 5, that RTBV genomic sequence variation is widely reported, and that direct strain variant descendants may have low sequence homology, and that this variability is due to the quasispecies genetic population structure of this badnavirus. Cabauatan et al also teach for example on page 2236, column 2, lines 10-22 that large sampling of quasispecies genomic sequence structure would be required to determine sequences and their functional uses as derived from a badnavirus quasispecies genetic population structure. Regenmortel et al (2000. Virus Taxonomy: 7th Report of the International Committee on the Taxonomy of Viruses, Academic Press, NY) teach for example on page 9, lines 9-30, that a "quasispecies" genetic population structure consists of a population of variant sequences, which serve as reservoir of mutation for virus evolution and host adaptation within an infected cell, wherein the mutations are considered to be accumulated in part due to replicative machinery of the cell, typically of host and viral origin, which lack proofreading and/or high fidelity replicative mechanisms.

The use of chemical hybridization to identify a *Badnavirus* sequence is unpredictable. Lockhart et al (1993. pp. 105-113, In: Breeding banana and plantain for resistance to diseases and pests. CIRAD, Montpellier, France) teach for example on page 106, lines 26-page 107, line 2 that BSV has a very narrow host range , and is restricted to *Musa* and *Saccharum* species. Lockhart et al teach that the ability of BSV isolates to infect *Musa* or *Saccharum* species to cause disease is genotypic specific, within a *Musa* and *Saccharum* species, or between *Musa* and *Saccharum* plants, but that tolerance did not alter the ability of the virus to replicate, as asymptomatically infected plants could transmit the virus via mealybugs. Lockhart et al (1993) teach for example on page 106, line 24 to page 107, line 2; and page 108, line 6 to page 110 line 2, that ScBV sequences cross hybridize with BSV some BSV sequences, and many isolate BSV sequences do not cross hybridize with other BSV sequences, with designation as BSV, and that nucleic acid hybridization between viruses characterized as BSV, by their initial identification in banana, are unpredictable in identifying strains of the virus as it is delimited by particle morphology.

The functional promoter capabilities of a polynucleotide comprising a promoter consisting of sequence from 5' sequence upstream of the ORF3 open reading frame of badnaviruses is unpredictable for conferring expression in all plant cells from all tissue types. Olszewski et al (1999. WIPO International Publication Number WO 9909190) teach for example in Figures 2-3 on pages 60-61; on page 34, lines 12-18; and on page 7, line 20 to page 8, line 5; the making of three promoter sequence ranges corresponding to nucleotides 5999-7205, 5999-7299, and 5999-7420 of *Sugarcane bacilliform virus* (ScBV), respectively designated as the ScBV-1 , ScBV-2, and ScBV-3 promoters. Olszewski et al (1999) teach for example in Table 3 on page 40; in Table 4 on page 41; on page 8, lines 3-5, that a ScBV-3 promoter fragment corresponding to nucleotides 5999-7420 of *Sugarcane bacilliform virus* (ScBV) promoter extending 5' from the transcriptional start site of the transcript for ORF 3 of ScBV, when fused to a GUS transcribable sequence and transformed into oat plants, confers GUS expression only in vascular cells of leaves, but not in other leaf cells, and that no GUS expression is conferred by said ScBV-3 promoter in awn tissue. Olszewski et al (1999) teach for example in Table 6 on page 44 that the ScBV-3 promoter fragment corresponding to nucleotides 5999-7420 of *Sugarcane bacilliform virus* (ScBV) promoter extending 5' from the

transcriptional start site of the transcript for ORF 3 of ScBV, when fused to a GUS transcribable sequence and transformed into *Arabidopsis* plants, confers GUS expression only in vascular cells of sepals and siliques, but not in other sepal or silique cells, and that no GUS expression is conferred by said ScBV-3 promoter in awn tissue.

Furthermore, Chen et al (1996. J. Virol. 70(12):8411-8421) teach that nucleotide sequences upstream and downstream of the ORF3 translational start site impact the cell- and tissue-specific expression for an ORF3 promoter of a *Badnavirus*. Chen et al teach for example in the Abstract on page 8411; and in Figures 1-7 on pages 8413-8418; that positions +8 to +83 of ORF 3 of *Rice tungro bacilliform virus* (RTBV) are required for activation of transcription in certain plant cell types, and that the effect of sequences changes or deletions corresponding to sequences downstream or upstream of the transcriptional start site of the ORF 3 transcript, results in unpredictable promoter activity.

The determination of promoter functionality for the activation of transcription, on the basis of a percent sequence homology comparison, is unpredictable in any plant cell of any tissue type. For example, Izawa et al (1993, J. Mol. Biol. 230 :1131-1144) and Hao et al (1998, The J. of Biological Chemistry 273 (41): 26857-26861) teach that non-coding nucleic acid sequences that exhibit base pair deletions, substitutions or rearrangements, cannot be expected to maintain their promoter or enhancer activity. Izawa et al teach for example on page 1132, bottom of right column and page 1134, bottom of left column that the nucleotides flanking the G-box (CACGTC) and C-box (GACGTC) hexameric cores of a plant promoter unpredictably affect protein binding activity and specificity of bZIP transcription factors Furthermore, Hao, et al teach that the binding activities of ethylene-responsive element-binding proteins (EREBP) to their cis-element GCC box (AGCCGCC) is unpredictable when sequence variations are introduced. Hao et al teach (*supra*, pages 26857, abstract and 26860, left column, 2nd paragraph) that creating base-pair substitutions within the GCC box modulates binding specificity, implying that different positions within the GCC box are important for differential binding by different EREBP's, in particular, substituting T's for the two G's eliminates binding completely.

Applicants fail to provide guidance for which bases of SEQ ID NO:2 can be altered and still maintain proper spatial and temporal constitutive expression. Applicants fail to provide guidance for the length of the broadly claimed polynucleotide, and how a promoter comprising

additional bases added 5' and 3' to the sequence consisting of SEQ ID NO: 2 , when compared to the promoter fragment consisting alone of SEQ ID NO:2, would impinge upon the broadly claimed expression pattern in any plant cell of any tissue type as broadly claimed. Furthermore, applicants fail to provide guidance for which bases can be deleted and which regions of the sequence can tolerate additions, base-substitutions or recombinations and still be a functional promoter as broadly claimed. Applicants fail to disclose guidance as to the sequence composition for the broadly claimed variable polynucleotide sequence, which would have the recited characteristics of the claims. Applicants fail to disclose any structural features of the promoter upstream or downstream of the ORF 3 transcription start site, and it remains unclear what features identify the broadly claimed promoter, including an isolated and purified nucleic acid comprising the broadly claimed variable sequence promoter and a nucleotide sequence that encodes a nonspecified transcribable sequence.

Applicants fail to disclose guidance for the totality of starting materials that are essential subject matter for the broadly claimed plants of all plant species. Applicants fail to disclose transgenic plant cells, plant propagules, or plant s and parts thereof, for expression in either all cells of all tissue types , or all plants that exhibit expression in all cell types of all plant species as broadly claimed, or all plant cells of all tissue types in the *Musaceae*.

Therefore, given the breadth of claims, unpredictability, and lack of guidance in the instant specification as discussed above, undue experimentation would have been required of one of skill in the art to make and/or use: the multitude of allelic polynucleotide sequence variants of the BSV promoter of unspecified length; the multitude of polynucleotide sequence variants drawn to a sequence that hybridizes under conditions of unspecified stringency; the multitude of ~~the multitude of~~ sequence variants with 75 % identity; the multitude of sequence variants of polynucleotides identified by a "strain" designation; and the multitude of transformed plant cells of any tissue, plant propagules, plants of any species and parts thereof.

Claims 1 and 3-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant fails to provide guidance for the identification of structural features unique to broadly claimed variable polynucleotide sequence of a promoter derived from SEQ ID NO:2, , the functional domains of the broadly claimed promoter of variable sequence, and the overall function of the broadly claimed variable sequence promoter, and fails to provide guidance for the making the broadly claimed plant cells, plants and parts thereof, and plant propagules transformed with said variable polynucleotide. Given the lack of description for the broadly claimed promoter derived from SEQ ID NO:2, which comprises nonspecified and undisclosed sequence length and composition, it remains unclear what features identify the broadly claimed promoter, including an isolated and purified nucleic acid comprising the broadly claimed variable sequence promoter and a nucleotide sequence that encodes a nonspecified transcribable sequence. Furthermore, in consideration of the variability of naturally occurring pararetroviruses as they exist in quasispecies, as discussed in the 35 U.S.C. 112 enablement rejection above and the 35 U.S.C. 102(e)/103(a) rejection below, the designation of a sequence on the basis of its designation as ScBV or BSV, or as a strain thereof, provides no structural distinction for the polynucleotide sequences as broadly claimed.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

The disclosure of the instant specification fails to provide an adequate written description to support the genus as broadly claimed for the polynucleotides; and transformed plant cells, plant propagules, and plants and parts thereof comprising said polynucleotides.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 3-4 and 7 are rejected under 35 U.S.C. 102(b) as anticipated by Lockhart et al (1986. Phytopathology (76)10:995-999) and Lockhart et al (1993. pp. 105-113, In: Breeding banana and plantain for resistance to diseases and pests. CIRAD, Montpellier, France).

Claim 3 is broadly drawn an isolated polynucleotide which hybridizes under conditions of unspecified stringency with a polynucleotide having the sequence of SEQ ID NO:2. A "transcribable sequence" is interpreted to include the ORF 3-derived polynucleotide sequences of other West African BSV isolates. Claim 4 is broadly drawn to an isolated nucleotide which has an ORF 3 upstream promoter sequence found in any strain of *Banana streak virus*. Claim 7 is broadly drawn to a polynucleotide sequences comprising SEQ ID NO: 2, a fragment thereof, and any allelic variant sequence of SEQ ID NO:2, whose length is unspecified, but whose limitation is that is operably linked to any transcribable sequence, to promote transcription in a *Musaceae* cell.

Lockhart et al (1993) teach for example in Figures 6 and 7 on page 109; in Figures 8-11 on page 110; in Figure 13 on page 112; and on page 108, line 24 to page 111, line 4, the isolation of BSV genomic polynucleotide sequences of various West African isolates of BSV, and the use of isolated polynucleotide fractions in assays of BSV infectivity of virus actively replicating in host tissue.

Lockhart et al (1986) teach for example in Figures 5 and 6 on page 997; on page 995, column 2, lines 9-24; and on page 997, column 1, lines 2-38, and page 998, column 2, lines 1-4, the isolation of BSV genomic polynucleotide sequences of a Moroccan isolate of BSV in an assay of BSV active replication in host tissue.

The ability of the promoter sequence taught by Lockhart et al (1986) and Lockhart et al (1993) to hybridize with SEQ ID NO: 2 under conditions of unspecified stringency would have been ~~and~~ an inherent property.

Claims 1 and 3-20 are rejected under 35 U.S.C. 102(e) as anticipated by Olszewski et al (1999. US Patent No. 5,994,123 filed on 9 August 1996) in light of Lockhart (1993) and Regenmortel et al (2000. Virus Taxonomy: 7th Report of the International Committee on the Taxonomy of Viruses, Academic Press, NY).

Claim 1 is drawn to an allelic variant sequence of SEQ ID NO:2 of undisclosed length, or a fragment thereof, which when operably linked to a transcribable sequence, promotes transcription in any *Musaceae* cell. Claim 3 is broadly drawn an isolated polynucleotide which hybridizes under conditions of unspecified stringency with a polynucleotide having the sequence of SEQ ID NO:2. Claim 4 is broadly drawn to an isolated nucleotide which has an ORF 3 upstream promoter sequence found in any "strain" of *Banana streak virus* (BSV). Claim 6 is a nucleic acid comprising any length promoter sequence of a polynucleotide sequence of any one of Claims 1, 3, and 5, and any non-*Banana streak virus* sequence. The "non-Banana Streak Virus" sequence is interpreted to include an SBV sequence. Claim 7 is broadly drawn to a polynucleotide sequences comprising SEQ ID NO: 2, fragment thereof, and any allelic variant sequence of SEQ ID NO:2, whose length is unspecified, but whose limitation is that is operably linked to any transcribable sequence, to promote transcription in a *Musaceae* cell. Claims 8-9 are broadly drawn to nucleic acid vectors. Claims 10-20 are broadly drawn to plant cells and plants transformed with the polynucleotides, and methods of making the plants.

Olszewski et al teach in claims 1-15 ~~of the claims~~ an isolated and purified DNA segment comprising a *Sugarcane bacilliform virus* promoter selected from the groups consisting of SEQ ID NO: 3, SEQID NO:4, and SEQ ID NO:5, or a biologically active variant or fragment thereof which initiates transcription, wherein the DNA segment does not encode a sugarcane bacilliform virus polypeptide, and expression cassettes comprising said promoter ligated to a transcribable sequence. Vectors and transformed cells are taught in columns 20-26. The ability of the promoter sequences of Olszewski et al, or their variants, to hybridize to instantly claimed SEQ ID NO:2 under conditions of unspecified stringency, would have been a an inherent property. Furthermore, some of the sequences taught by Olszewski et al would be at least 75 % identical to instantly claimed SEQ ID NO:2.

In light of Regenmortel et al and Lockhart et al (1993), both BSV and *Sugarcane bacilliform virus* are interpreted as members of the *Badnavirus* genus which given the physical and serological heterogeneity within and between BSV and ScBV designations, and common biological characteristics as indicated by the same disease symptomology in the same restricted host range of sugarcane and banana, a designation of a virus as BSV or ScBV on the basis of the host in which it is initially identified, does not distinguish these designations as distinct groups or species.

The current taxonomy of the genus *Badnavirus* as stipulated in the Seventh Report of the International Committee on Virus Taxonomy (ICTV), taught by Regenmortel et al on page 343, lines 11-15 are that the criteria to demarcate species in the genus *Badnavirus* are: 1) differences in host range; 2) differences in genome nucleotide composition of more than 50%; and 3) differences in gene product sequences. Applicant discloses for example in Table 1 on Page 61, and on pages 65-68 of the instant specification, that the full length ScBV exhibits 48.8% sequence difference from the full length BSV sequence of SEQ ID NO: 1, which is not a species distinction for BSV or ScBV. Furthermore, Regenmortel et al teach that on page 7, line 27 to page 9, line 40, that viral groups whose replicative cycle pass through an RNA encoded genomic phase, which would include pararetroviral forms, typically exist within plant cells as "quasispecies". Regenmortel et al teach for example on page 9, lines 9-30, that a "quasispecies" consist of a population of variant sequences, which serve as reservoirs of mutation for virus evolution and host adaptation within an infected cell, wherein the mutations are considered to be accumulated in part due to replicative machinery of the cell, typically of host and viral origin, which lack proofreading and/or high fidelity replicative mechanisms. Applicants acknowledge on page 55, lines 9-22 of the instant specification that BSV viral genomes are integrated into the banana genome, consistent with their designation as pararetroviral viruses, as disclosed for example on page 2, lines 8-16, consistent with this interpretation.

Furthermore, in light of Lockhart et al (1993), a virologist of ordinary skill in the art would know that : members of the *Badnavirus* genus are serologically and genotypically heterogeneous within their host plants; viruses designated as *Banana streak virus* (BSV) and *Sugarcane bacilliform virus* have identical natural plant species host ranges of sugarcane and banana species; BSV- and SCBV-designated viruses are vectored in the field by mites; ScBV-

designated viruses cause banana streak disease and symptomology in bananas; and BSV-designated viruses cause indistinguishable disease in sugarcane, from disease caused by ScBV-designated viruses. Lockhart et al (1993) teach for example in Figures 6-7 on page 109; in Figures 8-11 on page 110; in Figure 13 on page 112; on page 106, line 24 to page 107, line 2; and on page 108, line 6 to page 11, line 4, the heterogeneity of nucleotide sequence and serology, identical host ranges, insect vectors, identical host ranges, and proximity of sugarcane and banana grown as subtropical crops, which confound the designation of the pararetroviruses known as BSV or *Sugarcane bacilliform virus* (ScBV). Lockhart et al (1993) further teach for example on page 108, line 6 to page 11, line 4, that no reliable means of distinguishing a BSV isolate from a ScBV isolate were available at the time the invention was filed. Lockhart et al (1993) teach for example on page 106, line 24 to page 107, line 2; and page 108, line 6 to page 110, line 2, that ScBV sequences cross hybridize with some BSV sequences, and many isolate BSV sequences do not cross hybridize with other BSV sequences. Furthermore, on the basis of sequence homology alone, in the absence of any other distinguishing characteristics, an arbitrary assignment of a named designation of SBV or BSV, does not interpret these virus populations as different virus species or different strains, but rather different sequences selectively assayed and sampled from a subset of quasispecies of a population of a badnavirus with overall indistinguishable biological characteristics.

Claim 2 is deemed free of the prior art, given the failure of the prior art to teach or suggest an isolated SEQ ID NO:2.

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francis Moonan, whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday 9:00 AM to 5:00 PM (E.S.T.)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ~~Paula Hutzell~~ Amy Nelson, can be reached at (703) ~~308-4310.~~ 306-3218. The fax phone number for this

Group is (703) 308-4315. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Francis Moonan, Ph. D.
22 March 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638